

“Flu Vaccine Production by the Thai GPO: *Economic Return VS National Security Concept* – Balancing Sustainability and Cost-Effectiveness”

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Introduction to the Kingdom of Thailand



The Kingdom of Thailand is located in the Continental Southeast Asia

- Total Population 63,396,000
- Life expectancy Male 70
Female 76
- GDP per capita (\$US) 3,200
- Universal Health Insurance with 100% coverage
- Free access to ARVs, RRT, and seasonal flu vaccination for high risk group
- Doctor and Bed per 10,000 population = 5 and 16



Situation & Preparedness in Thailand



- ❖ 2004 – Bird flu outbreak
- ❖ 2005 – National Security Program has started for flu vaccine products in Thailand
- ❖ 2007-2009
 - Thai Government allocated \$US 42 million for flu vaccine production project
 - WHO Collaboration for establishing R&D and flu vaccine production
 - GPO takes responsible as project principle and investment for running the project

Situation of H1N1 in Thailand



% Thai people infected **12.6 - 15.8**

Or approximately 8-10 million people

(estimated on 30.11.09 by the Bureau of Epidemiology, MOPH, Thailand)

Cumulative numbers of patient cases **29,921**

Cumulative numbers of death cases **192**

**Import of 2 million doses of PIIV at the cost of
\$US 18 million – starts immunization today (11
January 2010)** **(Status ; Jan,6,2010)**



Investment in Flu Vaccine Development & Production

(a) Pilot Plant – one BSL3 lab with GMP

Purpose : To build capacity on production & R&D of IIV and LAIV

Capital investment since 2007, supported from:

1. WHO: \$US 4.05 million with support also from the USG
2. GPO : \$US 0.5 million for management & labor Cost

(b) Industrial-scale Plants – one IIV and one LAIV plant

Target : Adequate sustainable capacity to respond to Flu pandemic

- 2 to 10 million doses of Trivalent IIV annually
- 10 million doses of Trivalent LAIV annually

Capital investment supported from Thai Government :

- IIV plant \$US 42 million (2007-2011)
- LAIV plant \$US 8 million (2010-2012)



Rationale for Investment



The principle rationale is “**National Security**”

The additional purposes are to:

- Support “**Sub-regional/Regional Security**”
- Capacity building for self reliance

There is “**no commercial purpose**” – **No concrete estimation of the return on investment at the beginning**



Prepared local demand to sustain the factories

- The National Health Security Board approved seasonal flu vaccine coverage for the high risk groups since 2008 covering 4 million people within 3 years (2011)
- The IIV plant will start to produce this amount of vaccine in 2012 to respond to local demand. This will allow sustainability and continuity of the capacity



H1N1 2009 PLAIV Production



- a. Technology transfer:** Pre-master seed from Institute of Experimental Medicine (IEM), Russia and production technology from WHO
- b. Yield :** **15-20 doses/egg** (titer = $7.5 \log \text{EID}_{50}/0.5 \text{ ml}$) - current stock of around 1.5 million doses
- c. Stability :**
 - Concentrated vaccine (-80°C) – 12 weeks
 - Finished vaccine in (-20 °C and 2-8 °C) – 6 weeks
- d. Clinical Trial:**
 - Phase I (part A) (toxicity test - 24 subjects) – 18 December 2009 – no immediate toxicity found
 - Phase II (part B) (toxicity and immunogenicity - 400 subjects) – starts at the end of February 2010



Flu Vaccine Cost Comparison in Thailand



Cost per dose vaccine (\$ US)			
Seasonal flu vaccine		Pandemic flu vaccine	
Import	GPO	Import	GPO
6	3.5	7.35 (IIV)	~1 (PLAIV)

Our Public Spirit on the Pandemic



- The GPO Board of Directors agreed to **donate** all H1N1 2009 PLAIV to the Thai government at no cost
- GPO committed to share 10% of PLAIV to WHO at no cost



Conclusion : Thanks to the Pandemic



- a. Thai government commitment to invest on flu vaccine R&D and production capacity in a sustainable manner.
- b. Commitment from international partners to support technology transfer to developing countries, including Thailand – WHO supported by USG, ADB, etc.
- c. Capacity building of the Thai GPO on the production of the Flu vaccine for “National Security” purpose.
- d. Increase access to seasonal Flu vaccine among Thais





Thank you for your attention